IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE VIROPHARMA INCORPORATED SECURITIES LITIGATION	CIVIL ACTION NO. 12-2714

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS THE AMENDED CLASS ACTION COMPLAINT

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I. INTRODUCTION

In this lawsuit, Plaintiff uses hindsight to try to convert an adverse regulatory determination by the Food and Drug Administration into a securities fraud claim. The gravamen of Plaintiff's Amended Class Action Complaint is that ViroPharma Incorporated ("ViroPharma") wrongly opined on the interpretation of a new statute permitting regulatory exclusivity to companies that invest in new clinical studies of previously approved antibiotic drugs.

Courts routinely reject as "fraud by hindsight" efforts to base securities class actions on predictions about future agency actions that later prove to be wrong. Here, Plaintiff's claim that ViroPharma knew or was reckless in not knowing how the FDA would rule is even more attenuated because the issue before the agency was a matter of first impression, and the heightened standard the FDA ultimately adopted had never before been announced or applied. Plaintiff cannot avoid this simple fact, nor does it have an answer for the extensive risk disclosures provided by ViroPharma in connection with its forward-looking statements.

The product at issue in this case is Vancocin, an antibiotic approved for the treatment of clostridium difficile associated diarrhea ("CDAD"), a potentially fatal condition. Before Congress passed the QI Program Supplemental Funding Act of 2008 (the "QI Act"), so-called "old antibiotics" such as Vancocin were not eligible for the additional three-year period of exclusivity afforded to other drugs under the Federal Food Drug & Cosmetic Act ("FD&C Act"). With its passage in 2008, the QI Act extended those rights to old antibiotics. The QI Act included a provision stating that exclusivity "shall not apply to any condition of use" for which the drug was approved before the statute's effective date. That provision is at the heart of Plaintiff's fraud claim.

In response to the incentives created by Congress, ViroPharma made a substantial investment to acquire the rights to data from clinical studies that provided clinically relevant new information regarding Vancocin's safety and efficacy. ViroPharma then filed a supplemental New Drug Application ("sNDA") seeking the FDA's approval to modernize the Vancocin label based upon that information. The FDA approved ViroPharma's sNDA on December 14, 2011, and posted the Approval Letter on its website.

The company's press release announcing the FDA's approval summarized the changes to Vancocin's label and disclosed ViroPharma's belief that, based upon those changes, the requirements for exclusivity had been met. ViroPharma also made clear—both in the body of the press release and in the extensive warning section at the end of the document—that the decision whether to grant exclusivity "resides with the FDA" and that there could be no assurances that the agency would "confirm our belief that Vancocin meets the requirements for, and thus has received, three years of exclusivity." The press release also expressly disclosed the risk that exclusivity might be denied and that Vancocin could face generic competition if the FDA also granted marketing approval to potential generic competitors.

Analysts' reactions were mixed. Some shared ViroPharma's belief that the FDA would grant exclusivity based upon the FDA-approved changes to the label; others speculated that the agency would deny exclusivity. Ultimately, on April 9, 2012, the FDA announced its decision that ViroPharma would not be granted exclusivity; in the same decision, the agency approved the applications of three competitors of ViroPharma to market generic versions of Vancocin. The company's stock price dropped, and this lawsuit followed.

Before evaluating ViroPharma's exclusivity request, the FDA had never before interpreted the QI Act provision regarding "conditions of use." In interpreting that provision for the first time, FDA concluded that it is not enough that the changes to the label relate to new (*i.e.*, not previously approved) "conditions of use." Rather, in the agency's view, in addition to being "new," conditions of use for old antibiotics also must be "significant." Thus, not only had the standard that the FDA used to deny exclusivity never before been described or applied, ViroPharma's request was subject to an interpretation that included a subjective component that is not found anywhere in the express language of the statute. In subsequent litigation over that standard, in which the district court gave deference to the agency's interpretation, the court concluded that the statutory language in the QI Act presented "an issue of first impression," recognized that the operative language was "ambiguous," and acknowledged that the FDA's decision "'involve[d] a subject matter that is technical, complex, and dynamic.'" *ViroPharma, Inc. v. Hamburg*, No. 12–0584, 2012 WL 1388183, at *12, *16 (D.D.C. Apr. 23, 2012).

Plaintiff nevertheless claims that at the time ViroPharma issued its December 14, 2011 press release Defendants knew or were reckless in not knowing that the sNDA did not satisfy the FDA's yet-to-be-adopted standard, and asserts that the company intended to mislead the market for the brief period before the FDA's decision would be announced.

Plaintiff has failed to plead a violation of Section 10(b) of the Securities Exchange Act of 1934, 15 U.S.C. § 78j(b), for the following reasons, each of which, standing alone, is dispositive:

- First, ViroPharma's statements are protected under the safe harbor enacted as part of the Private Securities Litigation Reform Act of 1995 ("PSLRA"). The challenged statements are forward-looking statements; were plainly identified as such at the time; and were accompanied by meaningful risk warnings. Consequently, regardless of whether ViroPharma actually knew what the FDA would ultimately do (which was not possible, and is expressly denied), the statements are not actionable.

- Second, Plaintiff has not alleged a material misstatement or omission. All of Plaintiff's fraud claims turn upon the alleged failure to disclose the contents of the FDA's December 14, 2011 Approval Letter and four earlier communications with the FDA that led to that approval. First, there was no duty to disclose those communications because (a) the Approval Letter ***was*** publicly available; and (b) ViroPharma did not make any statements about exclusivity before receiving the Approval Letter and had no independent duty to disclose the interim communications. Second, those communications were ordinary course discussions to determine the content and language of Vancocin's new label. They did not address, expressly or impliedly, the exclusivity standard the FDA would ultimately adopt or whether the changes to Vancocin's label would meet it.

- Third, Plaintiff has not pled a strong inference of scienter. Plaintiff has failed to plead facts establishing (a) that ViroPharma knew or was reckless in not knowing the standard the FDA would later adopt based on a statutory provision that had never before been interpreted; or (b) why ViroPharma would knowingly and falsely predict what the FDA would do when the outcome of the agency action would be revealed in mere months. Moreover, Plaintiff's allegations of scienter cannot be reconciled with ViroPharma's actions during the putative class period, during which it purchased over 1.6 million shares of its own common stock at supposedly inflated prices.

Accordingly, Plaintiff's Section 10(b) claims—Counts I and II of the Complaint—should be dismissed. Because Plaintiff has failed to state a Section 10(b) claim, its Section 20(a) claim—Count III—should be dismissed as well.

II. FACTUAL ALLEGATIONS AND BACKGROUND[1]

A. Background

Lead Plaintiff Carpenters' Local 27 Defined Benefit Fund is a ViroPharma shareholder that allegedly purchased shares while the company's stock price was artificially inflated. ¶ 30. Based outside of Philadelphia, defendant ViroPharma is a biotechnology company "dedicated to the development and commercialization of products that address serious diseases." ¶ 31; *see also* ¶ 37. Defendant Vincent J. Milano is ViroPharma's President and Chief Executive Officer as well as Chairman of the Board of Directors, ¶ 32; defendant Charles A. Rowland, Jr. is ViroPharma's Vice President and CFO, ¶ 33; defendant Thomas F. Doyle is ViroPharma's Vice President, Strategic Initiatives, ¶ 34; and defendant J. Peter Wolf is ViroPharma's Vice President, General Counsel and Secretary. ¶ 35.

[1] Defendants accept as true the well-pled factual allegations in Plaintiff's Amended Class Action Complaint ("Complaint"), as they must on a motion to dismiss, but reserve their right to challenge these averments should any claims survive this motion. Citations to "¶__" refer to the numbered paragraphs of the Complaint. Throughout this Memorandum, all citations are omitted in any quote unless noted otherwise.

One of ViroPharma's products is Vancocin, which is an antibiotic used to treat CDAD, "a severe infection of the gastrointestinal tract that, left untreated, can result in death. The incidence of CDAD increased more than tenfold since 1982, and Vancocin was the only drug approved by the FDA to treat the condition." ¶ 2.

B. ViroPharma's Citizen Petition

Because patent protection for Vancocin expired in 1996, ¶¶ 4 n.2, 37, Plaintiff alleges that the only barrier to generics entering the market was an FDA requirement that, as a condition for approval, generic versions of Vancocin be tested on humans in order to demonstrate bioequivalence. ¶ 4.

In 2006, the FDA changed its position regarding the proof necessary to establish bioequivalence. ¶¶ 5, 50. Employing an administrative procedure for raising concerns with the FDA, ViroPharma submitted a Petition for Stay of Action on March 17, 2006 (the "Citizen Petition") asking the agency to refrain from approving applications to allow the marketing of a generic version of Vancocin "in the absence of evidence that the Agency has established and applied appropriate standards." Ex. 1, Citizen Petition at 1; *see* ¶¶ 6, 52.[2]

Plaintiff alleges that ViroPharma used the Citizen Petition and subsequent amendments both to "attack the FDA's decision, and as a means to stall generic competitors from entering the market." ¶¶ 7, 52. Plaintiff also alleges that the FDA was required to respond to the Citizen Petition before granting marketing approval to generics. ¶ 53.[3]

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[2] It is appropriate for the Court to consider on a motion to dismiss the full text of documents referenced in the Complaint. *In re Advanta Corp. Sec. Litig.*, No. 97-CV-4343, 1998 WL 387595, at *5 n.10 (E.D. Pa. July 9, 1998) ("In analyzing securities fraud claims, review of the full text of documents cited in plaintiffs' complaint is appropriate.") (citing *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997)), *aff'd,* 180 F.3d 525 (3d Cir. 1999). As the Supreme Court explained in *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007), when deciding a motion to dismiss, "courts must consider the complaint in its entirety, as well as other sources . . . in particular, documents incorporated into the complaint by reference, and matters of which a court may take judicial notice."

[3] Plaintiff's irrelevant and inflammatory accusations are wrong as a matter of law. As the FDA observed with

C. The QI Act

Plaintiff alleges that ViroPharma also sought to forestall generic competition through a law that provides companies with exclusive rights with respect to certain advancements in their product labels. Because generic companies are required to copy the product label of the referenced branded drug (subject to limited exceptions), exclusivity as to the label can translate into marketing exclusivity for a period of time. It is that exclusivity, and ViroPharma's statements about how it might apply to Vancocin, that is at the core of Plaintiff's fraud claims.

Under the FD&C Act, a company must file a New Drug Application for permission to market a new, branded pharmaceutical product. ¶ 44. To make substantive changes to the label of an already-approved product, companies must file an sNDA. *Id*. The FD&C Act provides that a generic version of a drug will not be approved for three years after an sNDA is approved if the sNDA contained "reports of new clinical investigations (other than bioavailability studies) essential to the approval of the supplement and conducted or sponsored by the person submitting the supplement." 21 U.S.C. § 355(c)(3)(E)(iv); 21 U.S.C. § 355(j)(5)(F)(iv). Before 2008, drugs like Vancocin, which were classified as "'old antibiotics,'" were not eligible to apply for three years of exclusivity under this provision. ¶ 58.

In October 2008, Congress passed the QI Act. The QI Act made three year exclusivity available to old antibiotics, 21 U.S.C. § 355(v)(1)(A), for changes approved in an sNDA if the sNDA "contains reports of new clinical investigations . . . essential to the approval of the [sNDA] and conducted or sponsored by the [applicant]." 21 U.S.C. § 355(j)(5)(F)(iv); *see* ¶ 59

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respect to another Citizen Petition filed in 2006, "[t]he law does not allow FDA to refuse to approve an ANDA because we have not responded to a petition. Section 505(j)(4) of the Act states that we shall approve an ANDA unless FDA identifies a deficiency expressly delineated in the Act." FDA Response to Endo Pharma. Citizen Petion, Dkt. No. FDA-2006-P-0346 (Aug. 22, 2012); *see also* 21 C.F.R. § 10.35(d) (petitioning the FDA does not "stay or otherwise delay any administrative action" unless the FDA determines the stay is in the public interest or a statute or court requires it).

(the QI Act "created a limited opportunity for a company with an Old Antibiotic to obtain Hatch-Waxman marketing exclusivity"), ¶¶ 9 n.3, 58 (identifying Vancocin as an Old Antibiotic).

For purposes of Plaintiff's claims here, the key language in the QI Act provides that exclusivity "shall not apply to any ***condition of use*** for which the [old antibiotic] was approved before [October 8, 2008,] the date of the enactment of [the QI Act]." 21 U.S.C. §355(v)(3)(B) (emphasis added); *see also* ¶ 60.

The Complaint cites excerpts from the legislative history to aver that the phrase "condition of use" was intended to refer only to new indications (*i.e.,* approval for use in specific disease states) for an old antibiotic. ¶¶ 60-63. However, Plaintiff does not aver – nor could it – that the FDA or any court had interpreted the meaning of "condition of use" in the QI Act at the time Defendants made the challenged statements.

D. ViroPharma Licenses Study Results

As a "first step" toward obtaining exclusivity for Vancocin, ViroPharma licensed data from clinical studies conducted by Genzyme Corporation. ¶¶ 10, 67. The Genzyme studies compared Genzyme's experimental drug tolevamer to Vancocin and another drug used to treat CDAD, metronidazole. ¶ 68. The studies did not support Genzyme's efforts to obtain approval of tolevamer, *id*., but did generate data that, when analyzed by ViroPharma, resulted in important "clinically relevant new safety and efficacy information" about Vancocin. Ex. 2, Dec. 14, 2011 Approval Letter ("Approval Letter") at 1, cited at ¶¶ 87-88. ViroPharma obtained an exclusive license to the study results in June 2009. ¶ 69.

E. ViroPharma's sNDA and Dialogue with the FDA

As a "second step," on April 23, 2010, ViroPharma submitted an sNDA to the FDA based on its analysis of the results of the Genzyme study. ¶¶ 11, 70. Thereafter, ViroPharma engaged in a dialogue with the FDA about its sNDA and the changes to Vancocin's label that

FDA would permit ViroPharma to make. The Complaint references and quotes four communications between ViroPharma and the FDA after the sNDA was filed but before approval was granted, copies of which are attached as Exhibits 3-6.[4] None of these communications refer or relate to the meaning of "condition of use" as used in the QI Act, which later became the determinative issue on exclusivity. The first communication, a February 18, 2011 Letter from the FDA, identified four issues related to pooling of study results, comparative effectiveness claims, a multiplicity of comparisons and bioequivalence. Ex. 3, Feb. 18, 2011 Letter at 1-2. The letter anticipated that ViroPharma would address the issues, *id*. at 2, and the second communication referenced in the Complaint shows that ViroPharma submitted a number of questions to which the FDA responded. Ex. 4, May 20, 2011 Letter.

In the May 20, 2011 Letter, ViroPharma explained that "no comparative claims are being made in the proposed labeling" and "references to metronidazole [another drug used to treat CDAD] were removed." *Id*. at 2. Lest any confusion remain, the third communication cited in the Complaint "confirmed that no reference will be made to metronidazole in the Vancocin capsule labeling and that no comparative claims versus metronidazole are being proposed." Ex. 5, May 24, 2011 Teleconference Minutes at 2. The fourth communication, a teleconference regarding labeling on December 8, 2011 (as reflected in an internal FDA memorandum dated April 9, 2012), reiterated that only descriptive, and not comparative, efficacy claims would be included in the new label. Ex. 6, Apr. 9, 2012 Memorandum at 10.

There is no reference to exclusivity in any of these exchanges with the FDA, nor is there any link between the changes to the label discussed in those exchanges and how the FDA would later interpret the phrase "condition of use" in the QI Act.

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[4] Ex. 3, Feb. 18, 2011 Letter cited at ¶¶ 75-77; Ex. 4, May 20, 2011 Letter cited at ¶¶ 78-79; Ex. 5, May 24, 2011 Teleconference Minutes cited at ¶ 80; Ex. 6, Apr. 9, 2012 Memorandum referring to Dec. 8, 2011 Teleconference cited at ¶¶ 81-83.

F. The FDA Approves the sNDA

Demonstrating that the issues highlighted by Plaintiff were ultimately resolved to the FDA's satisfaction, the FDA approved the sNDA on December 14, 2011. Ex. 2, Approval Letter. The Approval Letter specifically states that the sNDA "provides for updates to the prescribing information for VANCOCIN with ***clinically relevant new safety and efficacy information***." Ex. 2, Approval Letter at 1 (emphasis added). Like the correspondence that preceded it, the Approval Letter did not address Vancocin's eligibility for exclusivity or offer any insights into how the FDA would ultimately interpret and apply the QI Act.

The Complaint emphasizes the FDA's statements in the Approval Letter with respect to the Pediatric Research Equity Act ("PREA"), but nothing in the Approval Letter suggests that PREA was linked to eligibility for exclusivity. Moreover, critically, Plaintiff constructs its fraud theory based upon the mistaken belief that the Approval Letter "was not publicly available until after the Class Period." ¶ 72 n.36. Contrary to Plaintiff's assertion, the Approval Letter ***was*** publicly available the day after it was issued, as recently confirmed by the FDA. Ex. 7, Forgues Aff., Dec. 7, 2012.[5]

G. ViroPharma's Statements After sNDA Approval

Plaintiff does not allege that Defendants made any statements about potential exclusivity before the FDA approved the changes to Vancocin's label. Rather, Plaintiff challenges seven statements made after the sNDA was approved, claiming that those statements were materially false and misled the market about the likelihood that the FDA would grant Vancocin three years of exclusivity. The challenged statements are contained in: (1) the December 14, 2011 Press

[5] Courts may take judicial notice of documents produced in response to a Freedom of Information Act request. *In re Am. Apparel, Inc. S'holder Litig.*, 855 F. Supp. 2d 1043, 1064 (C.D. Cal. 2012) (citing *Silverstrand Invs. v. AMAG Pharm., Inc*., No. 10-10470, 2011 WL 3566990, at *4 (D. Mass. Aug. 11, 2011)); *Krzesniak v. Cendant Corp*., No. 05-05156, 2007 WL 640594, at *2 (N.D. Cal. Feb. 27, 2007).

Release announcing the approval of the sNDA; (2) a petition that ViroPharma submitted to the FDA on December 22, 2012 in support of its exclusivity position; (3) the January 5, 2012 Press Release announcing earnings guidance; (4) statements at a January 11, 2012 healthcare conference; (5) the February 28, 2012 Press Release announcing operating results and reiterating its earnings guidance; (6) statements during a February 28, 2012 earnings call; and (7) portions of the February 28, 2012 10-K describing ViroPharma's expectations for the future, attached as Exhibits 8-14, respectively.

In the December 14, 2011 Press Release that begins the putative class period, ViroPharma summarized the changes that had been approved by the FDA; stated its ***belief*** that those changes satisfied the statutory requirements for exclusivity and opined on the effect that would have on the company's future performance; made clear that the FDA would ultimately make the judgment whether Vancocin was entitled to exclusivity; and included extensive and meaningful risk disclosures informing the market that the label changes might not result in exclusivity or forestall generic competition. Ex. 8, Dec. 14, 2011 Press Release, cited at ¶ 95. For example, in the December 14 Press Release, ViroPharma stated unequivocally: "***Ultimately, the decision on a grant of three-year exclusivity and its effect on generic vancomycin capsule approvals resides with the FDA***" and "***[t]here can be no assurance that: the FDA will confirm our belief that Vancocin meets the requirements for, and thus has received, three years of exclusivity . . . .***" *Id*. at 1, 3 (emphasis added).

As set forth in Section III.B below, each of the other challenged statements was similarly forward-looking and (with the exception of ViroPharma's Citizen Petition Supplement, which is addressed separately) repeated or incorporated essentially the same extensive cautionary language found in the December 14, 2011 Press Release, in which the consistent message was that responsibility for approval resided with the FDA and there was a risk that the agency might not agree with ViroPharma's assessment.

H. ViroPharma's Supplement to Its Citizen Petition

On December 22, 2011, ViroPharma filed a supplement to its Citizen Petition (the "CP Supplement") in which the company set forth its arguments to the FDA as to why Vancocin qualified for exclusivity. ¶¶ 21, 107-10. The Complaint alleges that the CP Supplement was a "final step" for obtaining exclusivity. ¶ 12.

I. ViroPharma's Stock Repurchase

Before and during the putative class period, ViroPharma was actively purchasing its own common stock. As reported in ViroPharma's February 28, 2012 10-K, ViroPharma repurchased shares starting in September 2011 and, during the fourth quarter of 2011, repurchased approximately 1.0 million shares at an average price of $20.62 per share at a cost of approximately $20.8 million. Ex. 14, Feb. 28, 2012 10-K at 61-62, 84, cited at ¶ 131. During the first quarter of 2012, when Plaintiff claims Defendants were intentionally inflating the stock price, ViroPharma ***increased*** its program, repurchasing approximately 1.6 million shares at an average price of $31.13 per share, at a cost of approximately $50 million. Ex. 15, May 1, 2012 10-Q at 15, 26, 36, 47.[6]

J. Analyst Reaction to the Approval of the sNDA

As reflected in the Complaint, numerous analysts commented on the potential for exclusivity. *See, e.g.*, ¶¶ 101-05. One analyst cited by Plaintiff, J.P. Morgan, acknowledged at the time that "'the decision on exclusivity will ultimately lie with the FDA.'" ¶ 101 (citing J.P.

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[6] A court may take judicial notice of SEC filings when deciding a motion to dismiss. *Oran v. Stafford*, 226 F.3d 275, 289 (3d Cir. 2000); *accord Johnson v. Radian Grp., Inc.*, No. 08-2007, 2010 WL 2136562, at *11 n.19 (E.D. Pa. May 26, 2010) (taking judicial notice of a 10-Q form); *In re NAHC, Inc. Sec. Litig.*, 306 F.3d 1314, 1331 (3d Cir. 2002) (finding "no reversible error and completely accept[ing] the district court's" reliance on "documents filed with the SEC, but not relied upon in the Complaint").

Morgan Report). Other analysts, notably ignored by Plaintiff, predicted that exclusivity would be denied. For example, in a December 15, 2011 Report, Cowen and Company stated: "[W]e interpret the FDA's regulations differently than ViroPharma, and we are skeptical that Vancocin is eligible for exclusivity based on this label change." Ex. 16, Cowen and Company Report, Dec. 15, 2011, at 1. Similarly, BioLogic Equity Research concluded: "We believe ViroPharma has virtually no chance of using the new Vancocin label to hold off generics." Ex. 17, BioLogic Equity Research Report, Dec. 15, 2011 at 1.[7] Thus, investors could draw their own conclusions from the public information and the divergent conclusions of analysts.

K. FDA's April 9, 2012 Decision

On April 9, 2012, the FDA responded to ViroPharma's Citizen Petition. The agency denied ViroPharma's claim for three year exclusivity and announced that it had approved the applications for three generic versions of Vancocin. Ex. 18, Apr. 10, 2012 Press Release at 1, cited at ¶ 137. In that decision, the FDA interpreted the QI Act for the first time and took the position that "in order for an sNDA for an old antibiotic such as Vancocin to be eligible for a grant of exclusivity, it must be a ***significant*** new use," *id*. (emphasis added), such as a new indication, a new dosing regimen, or "'***significant*** expansion in the conditions of use of the product' to new 'patient populations,'" *Hamburg*, 2012 WL 1388183, at *15 (emphasis added), even though the QI Act does not contain the word "significant." 21 U.S.C. § 355(v)(3).

[7] *Benak ex rel. Alliance Premier Growth Fund v. Alliance Capital Mgmt. L.P.*, 435 F.3d 396, 401 n.15 (3d Cir. 2006) (affirming district court's decision that a court may, in certain circumstances, take judicial notice of information "in the public realm" such as news reports to show inquiry notice); *Mollett v. Leith*, No. 09-1192, 2011 WL 5407359, at *3 (W.D. Pa. Nov. 8, 2011) (a court may consider documents outside of the complaint in ruling on a motion to dismiss); *In re Century Aluminum Co. Sec. Litig.*, Nos. 09-1001, 09-1103, 09-1162, 09-1205, 2011 WL 830174, at *9 (N.D. Cal. Mar. 3, 2011) (dismissing complaint and denying motion to strike certain analyst reports and noting that "courts routinely take judicial notice of analyst reports, not in order to take notice of the truth of the matters asserted therein, but in order to determine what may or may not have been disclosed to the public").

L. *Hamburg* Litigation

In response to the FDA's decision, ViroPharma promptly initiated litigation against the FDA in the U.S. District Court for the District of Columbia. Compl. at 1. On April 23, 2012, the court denied ViroPharma's request for a preliminary injunction but acknowledged that "ViroPharma's statutory exclusivity claim, which alleges that the FDA's letter ruling denying ViroPharma's Citizen Petition and its approval of vancomycin ANDAs are inconsistent with the FFDCA, presents ***an issue of first impression***." *Hamburg*, 2012 WL 1388183, at *11 (emphasis added). The Court found the statute to be "ambiguous" and deferred to the FDA's interpretation, particularly given that the subject matter was technical and complex. *Id*. at *14-16 (relying on *Chevron, U.S.A., Inc. v. Natural Res. Defense Council, Inc.,* 467 U.S. 837, 844 (1984)).

III. ARGUMENT

A. Legal Standards

To state a claim under Section 10(b), a plaintiff must allege (1) a "material misrepresentation (or omission)"; (2) "scienter, *i.e.*, a wrongful state of mind"; (3) "a connection with the purchase or sale of a security"; (4) "reliance" (*i.e.*, "'transaction causation'"); (5) "economic loss"; and (6) "'loss causation,' *i.e*., a causal connection between the material misrepresentation and the loss." *Dura Pharm., Inc. v. Broudo*, 544 U.S. 336, 341-42 (2005). Claims under Section 10(b) are subject both to Rule 9(b)'s requirement to plead fraud with particularity and the PSLRA's more "[e]xacting pleading requirements." *Tellabs*, 551 U.S. at 313; *see also Cal. Pub. Emps.' Ret. Sys. v. Chubb Corp*., 394 F.3d 126, 143 (3d Cir. 2004). A complaint that does not meet these standards must be dismissed. 15 U.S.C. § 78u-4(b)(1).

"In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b); *see also Institutional Investors Grp. v. Avaya, Inc*., 564 F.3d 242, 253 (3d Cir. 2009). Accordingly, a plaintiff must allege the "'who, what, when, where, and how'" of the alleged fraud. *In re Advanta Corp. Sec. Litig.*, 180 F.3d 525, 534 (3d Cir. 1999), *overruled in part on other grounds by Tellabs*, 551 U.S. 308 (2007). The PSLRA "imposes [yet] another layer of factual particularity to allegations of securities fraud." *In re Rockefeller Ctr. Props., Inc. Sec. Litig.*, 311 F.3d 198, 217 (3d Cir. 2002). It requires the complaint to "specify each statement alleged to have been misleading, [and] the reason or reasons why the statement is misleading." 15 U.S.C. § 78u-4(b)(1).

Additionally, the PSLRA requires a plaintiff to plead "with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2)(A). A "strong inference" of scienter is one that is "more than merely plausible or reasonable—it must be cogent and at least as compelling as any opposing inference of nonfraudulent intent." *Tellabs*, 551 U.S. at 314. The complaint must plead facts supporting this inference of scienter. *Winer Family Trust v. Queen*, 503 F.3d 319, 327 (3d Cir. 2007).

B. The Challenged Statements Are Protected and Not Actionable

1. The PSLRA's Safe Harbor for Forward-Looking Statements

The PSLRA contains a safe harbor provision under which certain "forward-looking statements" are, by definition, inactionable. 15 U.S.C. § 78u-5(c); *In re Aetna, Inc. Sec. Litig.*, 617 F.3d 272, 278-79 (3d Cir. 2010). To qualify for the safe harbor, a statement must be "forward-looking" as defined by the statute and either: "(1) identified as such, and accompanied by meaningful cautionary statements; or (2) immaterial; or (3) made without actual knowledge that the statement was false or misleading." *Id.* at 278-79; *see also* 15 U.S.C. § 78u-5(c). Because the statute is phrased in the disjunctive, "a defendant will be immune from liability if ***any one*** of its criteria is met." *In re ATI Techs., Inc. Sec. Litig.*, 216 F. Supp. 2d 418, 429 (E.D. Pa. 2002) (emphasis in original). As such, allegations that a misrepresentation was made knowingly will not defeat application of the safe harbor for clearly identified forward-looking statements accompanied by meaningful cautionary language or for forward-looking statements that are immaterial. *In re Anadigics, Inc. Sec. Litig.*, No. 08-5572, 2011 WL 4594845, at *30 (D.N.J. Sept. 30, 2011) ("Because we found that each of the forward-looking statements was accompanied by meaningful cautionary language . . . we need not address the question of whether they were made with actual knowledge that the statement was false and misleading."), *aff'd*, 2012 WL 4903355 (3d Cir. Oct. 17, 2012).

The PSLRA broadly defines a "forward-looking statement" to include "a statement of the plans and objectives of management for future operations, including plans or objectives relating to the products or services of the issuer" and "any statement of the assumptions underlying or relating to any" forward-looking statement. 15 U.S.C. § 78u–5(i)(1)(A)-(D); *Aetna*, 617 F.3d at 279. Courts note that "'a statement about the state of a company whose truth or falsity is discernible only after it is made necessarily refers only to future performance.'" *See, e.g.*, *In re Discovery Labs. Sec. Litig.*, No. 06-1820, 2006 WL 3227767, at *15 (E.D. Pa. Nov. 1, 2006) ("*Discovery Labs. I*"). Accordingly, courts repeatedly find that statements regarding the likelihood and timing of FDA approval for a drug and the reasons for management's beliefs that such approval will occur fall under the statutory definition of "forward-looking." *See, e.g.*, *id.* at *6-7, *16 (finding statements regarding the likelihood and timing of FDA approval for a drug and statements regarding the adequacy of the company's actions necessary for such approval were forward-looking under the safe harbor); *see also Kovtun v. VIVUS, Inc.*, No. 10-4957, 2012 WL 4477647, at *12 (N.D. Cal. Sept. 27, 2012); *In re Nuvelo, Inc., Sec. Litig.*, No. C 07-4056, 2008 WL 5114325, at *15 (N.D. Cal. Dec. 4, 2008); *Noble Asset Mgmt. v. Allos Therapeutics, Inc.*, No. CIVA-04CV-1030, 2005 WL 4161977, at *9 (D. Colo. Oct. 20, 2005); *In re Empyrean Bioscience, Inc. Sec. Litig.*, 255 F. Supp. 2d 751, 763-65 (N.D. Ohio 2003); *Meyer v. Biopure*

Corp., 221 F. Supp. 2d 195, 203-04 (D. Mass. 2002); *In re Columbia Labs., Inc. Sec. Litig.*, 144 F. Supp. 2d 1362, 1368-71 (S.D. Fla. 2001) (cases finding statements concerning and/or based on future FDA approval for a drug were forward-looking under the safe harbor).[8]

A statement can be expressly identified as forward-looking or one can "couch these statements in such terms that [their] forward-looking nature . . . would be self-evident to a reasonable investor." *In re Synchronoss Sec. Litig.*, 705 F. Supp. 2d 367, 401 (D.N.J. 2010); *see also In re Clorox Co. Sec. Litig.*, 238 F. Supp. 2d 1139, 1145 (N.D. Cal. 2002) ("a prediction about future events is self-evidently a forward-looking statement"). Moreover, for cautionary language to be "meaningful" as required by the first prong of the safe harbor, it must be specific; "a vague or blanket (boilerplate) disclaimer which merely warns the reader that the investment has risks will ordinarily be inadequate to prevent misinformation." *Avaya,* 564 F.3d at 256. Lastly, "[c]autionary language must be related to the forward-looking statements but need not actually accompany them." *In re NutriSystem, Inc. Sec. Litig.*, 653 F. Supp. 2d 563, 579 (E.D. Pa. 2009). Thus, language contained in SEC filings may be incorporated into press releases and conference calls. *Avaya*, 564 F.3d at 257-58.

2. Defendants' Forward-Looking Statements Are Protected Under the PSLRA's Safe Harbor

The statements at issue in this case are precisely the type of forward-looking statements that the PSLRA's safe harbor is designed to protect from lawsuits such as this where a plaintiff seeks to apply 20-20 hindsight when future results disappoint. Indeed, ViroPharma's statements

[8] Plaintiff cannot pull statements out of context that are clearly identified as forward-looking or involve discussions of future events and claim that they are not forward-looking because they are phrased in the present tense. *See, e.g.*, ¶ 184. These statements, regardless of how they were phrased, are assumptions underlying management's plans for Vancocin and thus are forward-looking under the statutory definition. 15 U.S.C. § 78u–5(i)(1)(B), (D); *In re Aetna, Inc. Sec. Litig.*, No. 07-4451, 2009 WL 1619636, at *22 (E.D. Pa. June 9, 2009) ("the fact that a statement is phrased in the present tense does not mean that it is not forward-looking"), *aff'd,* 617 F.3d 272 (3d Cir. 2010). When a present tense statement of current or historical fact "cannot meaningfully be distinguished from the future projection of which they are a part," the entire statement is forward-looking under the safe harbor. *Avaya*, 564 F.3d at 255.

about how it believed that the FDA would interpret and apply the law to the specific circumstances of the Vancocin sNDA, and how that would affect the company's future performance, could not have been anything but forward-looking. And, Defendants could not have been clearer about whose decision it was (the FDA's, not ViroPharma's) or the risk that exclusivity might be denied.

a. The December 14, 2011 Press Release

In the December 14, 2011 Press Release, Plaintiff challenges the statement that "ViroPharma believes Vancocin meets the requirements for, and thus has, three years of exclusivity, and that generic vancomycin capsules will not be approved during this period. Under FDA's regulations, labeling changes based on new clinical investigations that are essential to approval of the sNDA and to which the applicant has exclusive rights may be entitled to three years of exclusivity, and generic drug labeling cannot include information protected by such three-year exclusivity." ¶¶ 95, 96, 99. Plaintiff also challenges management's assumptions underlying their belief that the new label provided grounds for the FDA to grant exclusivity for Vancocin. ¶¶ 95, 98 (challenging the statement that "[t]hrough the sNDA approval, Vancocin's label for the first time includes clinical safety and efficacy data for Vancocin in treating currently circulating strains of Clostridium difficile, including the BI/NAP1 strain"); ¶ 97 ("today's sNDA approval . . . accomplishes an objective of the law to incent private industry to address a serious public health need—modernizing old antibiotic labeling"). These statements are management's beliefs about a ***future*** FDA decision as well as the assumptions underlying this belief, and they were identified as forward-looking: "Forward-looking statements provide our current expectations or forecasts of future events, including our belief that Vancocin meets the requirements for, and thus has received, three years of exclusivity . . . ." Ex. 8, Dec. 14, 2011 Press Release at 4.

Moreover, the press release contained extensive cautionary language tailored to the risks at issue and that more than suffices as "meaningful cautionary language" under the statute. For example, ViroPharma warned that:

> ***There can be no assurance that: the FDA will confirm our belief that Vancocin meets the requirements for, and thus has received, three years of exclusivity*** . . . that even if FDA agrees that the label changes contained in our approved sNDA warrant exclusivity that the FDA would agree that omission of the protected labeling would render generic versions of Vancocin less safe and effective, [or that] the FDA will agree with the positions stated in ViroPharma's Vancocin-related submissions . . . . ***In the event that the FDA does not grant three years of exclusivity in connection with the information updating our label through the approved sNDA,*** or decides that such protected labeling can be omitted from the label of a generic product, we cannot predict the timeframe in which the FDA will make a decision regarding either ViroPharma's citizen petition for Vancocin or the approval of generic versions of Vancocin. ***If the FDA does not grant such three year exclusivity,*** or if exclusivity is granted and a generic manufacturer is nonetheless permitted to omit the protected data . . . ***the threat of generic competition will be high***. The entry of competing generic products will significantly affect our sales of Vancocin and our financial performance. ***These factors . . . could cause future results to differ materially from the expectations expressed in this press release***.

Id. (emphasis added).

b. January 5, 2012 Press Release

In the January 5, 2012 Press Release Plaintiff challenges the statement that "'we believe Vancocin [] Capsules meets the requirements for, and thus has, three years of exclusivity and that generic vancomycin capsules will not be approved during this period'" as well as the "expected sales numbers Defendants projected for Vancocin for 2012" based on this belief. ¶¶ 113-15. Once again, these statements are forward-looking and were identified as such. Ex. 10, Jan. 5, 2012 Press Release at 3. The statements were accompanied by meaningful cautionary language that was virtually identical to that in the December 14, 2011 Press Release. *Id.* at 4.

c. January 11, 2012 J.P. Morgan Global Healthcare Conference

Plaintiff challenges Defendant Milano's statements at the January 11, 2012 J.P. Morgan Global Healthcare Conference that "'we created an exclusivity proposition'" for Vancocin, ¶ 119, and "'we believe we've gotten three years of exclusivity by taking advantage of the legislation that provides all the antibiotics three years of exclusivity, if you can update the label with meaningful safety and efficacy data, which we did,'" ¶ 120, and "'we're in a position now . . . to feel confident that we have exclusivity into the future with Vancocin.'" ¶ 121. Yet again, these statements reflect management's plans and objectives for Vancocin and the assumptions underlying those plans such that they fall within the statutory definition of "forward-looking." Such statements are self-evidently forward-looking. *Synchronoss*, 705 F. Supp. 2d at 401. Moreover, at the beginning of the conference, Milano stated "I encourage you to take out our SEC filings and read about the risks that are specific in our business." Ex. 11, Jan. 11, 2012 J.P. Morgan Conference Tr. at 1. ViroPharma's SEC filings in turn include the SEC Form 8-K attaching the December 14, 2011 Press Release and the SEC Form 8-K attaching the January 5, 2012 Press Release. Thus, the same meaningful cautionary language accompanying those press releases also applied to Milano's statements.

d. February 28, 2012 Form 10-K

Plaintiff challenges the statements in ViroPharma's February 28, 2012 10-K that "'[a]s a result of the sNDA approval, we believe Vancocin meets the requirements for three years of exclusivity, and that generic vancomycin capsules will not be approved during this period,'" that "'[w]e believe that attempting to omit Vancocin labeling changes protected by exclusivity would render generic versions of Vancocin less safe and effective,'" and that "'we expect future growth [to] be driven by sales of Vancocin.'" ¶ 133. These statements were forward-looking because they contained projected financials and reflected management's plans and objectives for

Vancocin and assumptions underlying those plans. Such statements are also self-evidently forward-looking. The February 28, 2012 10-K also contained extensive warnings that repeated and expanded on the language in the December 14, 2011 Press Release. *See generally* Ex. 14, Feb. 28, 2012 10-K at 6, 26-27, 31, 33-35, 67-68. For example, ViroPharma cautioned:

> If FDA's proposed bioequivalence method for Vancocin becomes effective, and either FDA does not agree that our labeling changes made effective through our sNDA warrant exclusivity, or FDA acknowledges such exclusivity but nonetheless determines that generic products would be no less safe or effective in the absence of such labeling changes, then the time period in which a generic competitor could be approved would be reduced and multiple generics may enter the market. The approval of generic copies of Vancocin would materially impact our operating results, cash flows and possibly intangible asset valuations.

Id. at 6, 27, 68. In addition, under the heading "***the FDA may not agree with our belief that Vancocin meets the requirements for three years of exclusivity, which could result in significant competition from generic products and lead to a significant reduction in sales of Vancocin,***" ViroPharma warned:

> The FDA may not agree with our position and may determine not to grant exclusivity . . . . [Additionally] FDA may conclude that the portion of Vancocin's updated label protected by exclusivity may nonetheless be omitted from the labels of generic products. ***Ultimately, the decision on a grant of three-year exclusivity and its effect on generic vancomycin capsule approvals resides with the FDA***.

Id. at 33 (first emphasis in original; second emphasis added); *see also id.* at 31 (warning of generic competition); 35 (noting the possibility that the "FDA does not agree that our labeling changes made effective through our sNDA warrant exclusivity"). These extensive warnings plainly constitute meaningful cautionary language under the safe harbor.

e. February 28, 2012 Press Release

Plaintiff next challenges statements in ViroPharma's February 28, 2012 Press Release that "'the approval of our Vancocin sNDA leading to modernized labeling and, we believe, three years of exclusivity,'" ¶ 126, as well as the company's "revenue 'guidance'" for future Vancocin sales. ¶ 127. Once again, these were forward-looking statements and were clearly identified as such. Ex. 12, Feb. 28, 2012 Press Release at 3-4. The press release included cautionary language similar to that in the December 14, 2011 Press Release. *Id.*

f. February 28, 2012 Earnings Call

Plaintiff also challenges statements in a February 28, 2012 earnings call. ¶¶ 128-30. First, Plaintiff challenges statements relating to ViroPharma's belief that it had obtained exclusivity. *See, e.g.*, ¶ 129 ("'in December [we] received the sNDA approval for Vancocin, which we believe merits three years of additional exclusivity,'" and "'[w]e remain confident that our sNDA warrants a three [] [year] exclusivity for the [] [reasons] that we've described'").

These statements were expressly identified as forward-looking at the beginning of the call. Ex. 13, Feb. 28, 2012 Earnings Call Tr. at 2 ("During this call we will make forward-looking statements . . . . [s]uch as those regarding our expectations for three years of additional exclusivity arising from the Vancocin sNDA approval."). Listeners were directed to the February 28, 2012 Press Release and to the company's SEC filings "for more information regarding the risks and uncertainties that could cause future results to differ materially from the expectations expressed in th[e] conference call." *Id*. at 2. As discussed above, these documents (which include the December 14, 2011 Form 8-K and Press Release, the January 5, 2012 Form 8-K and Press Release, and the February 28, 2012 10-K) contained extensive and meaningful cautionary language.

g. CP Supplement

Finally, Plaintiff challenges statements in ViroPharma's CP Supplement submitted to the FDA on December 22, 2011. Even assuming that Plaintiff could otherwise base a federal securities fraud claim on arguments in a petition to the FDA,[9] the alleged misrepresentations in ViroPharma's CP Supplement are inactionable under the second and third prongs of the safe harbor. *Aetna*, 617 F.3d at 278-279 (safe harbor applies to forward-looking statements that are "(2) immaterial; or (3) made without actual knowledge that the statement was false or misleading").

First, like the company's other statements about the prospects of exclusivity, the CP Supplement is self-evidently forward-looking. By its very nature, it is a request for future action by the FDA, not a representation that exclusivity had already been granted. No reasonable investor could have believed otherwise. *Glaxo Smithkline*, 2006 WL 2871968, at *10 (optimistic statement about strength of legal position "is a classic example of a forward-looking statement and is clearly protected as such."); *see also Discovery Labs. I*, 2006 WL 3227767, at *16 (statements about a company's product whose truth or falsity is discernable only after FDA decision are necessarily forward-looking).

Next, the CP Supplement meets the alternative conditions for protection in the second and third prongs of the safe harbor.[10] As further elaborated in Sections III.C and III.D below, Plaintiff has failed to allege a material misstatement or omission in the CP Supplement or that ViroPharma acted with actual knowledge that its statements to the FDA were false and misleading. Once again, Plaintiff is left with the untenable hindsight argument that ViroPharma somehow knew that it did not meet a heightened standard that had yet to be announced.

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[9] Courts have recognized that legal advocacy cannot support a fraud claim. *See, e.g., Costello v. Grundon*, 651 F.3d 614, 638 (7th Cir. 2011) ("the alleged misrepresentations were expressions of legal opinion, which cannot support a fraud claim"). "To hold that a legal position taken by a publicly traded company, or an expression of confidence in a legal position, may be converted by hindsight into an actionable misrepresentation if the company later loses the lawsuit would have a chilling effect on publicly traded companies seeking to defend their interests in litigation." *In re Glaxo SmithKline plc Sec. Litig.*, No. 05 Civ. 3751, 2006 WL 2871968, at *10 (S.D.N.Y. Oct. 6, 2006) (granting motion to dismiss securities fraud claims challenging statements concerning patent exclusivity).

[10] Not surprisingly, ViroPharma did not include in its petition the extensive cautionary language found in the company's press releases and the other challenged statements, as required for the first prong of the safe harbor -- it would have been absurd to tell the FDA in a petition seeking exclusivity that there was a risk that the FDA might not agree. However, cautionary language is not required to meet the alternative conditions in the second and third prongs of the safe harbor. *Aetna*, 617 F.3d at 279, 284; *ATI Techs.*, 216 F. Supp. 2d at 429.

* * *

Accordingly, all of the challenged statements are inactionable under the PSLRA safe harbor, and the Complaint should be dismissed on this ground alone.

C. Even If the Challenged Statements Were Not Protected by the PSLRA Safe Harbor, Plaintiff Fails to Allege the Existence of a Material Misrepresentation or Omission

In the Third Circuit, "'[a]n omitted fact is material if there is a substantial likelihood that a reasonable [investor] would consider it important in deciding how to [act].'" *In re Donald J. Trump Casino Sec. Litig.—Taj Mahal Litig.*, 7 F.3d 357, 369 (3d Cir. 1993). Material falsity is tested as of the time the statement is made. *Avaya*, 564 F.3d at 267 ("Shareholders have failed to plead with the requisite particularity the allegation that the October and January forecasts were false or misleading when made."); *see also NAHC*, 306 F.3d at 1330 ("To be actionable, a statement or omission must have been misleading at the time it was made; liability cannot be imposed on the basis of subsequent events."). Materiality may be decided as a matter of law on a motion to dismiss. *Aetna*, 617 F.3d at 283. Plaintiff claims all seven of the challenged statements are false because ViroPharma failed to disclose information that the FDA provided to it. ¶¶ 180-81. As described below, however, none of the alleged omissions or misrepresentations satisfies the materiality standard as a matter of law.

1. ViroPharma Had No Duty to Disclose the Allegedly Omitted Communications with the FDA

Claims based on nondisclosure of the Approval Letter fail because the letter was not concealed from investors. Accordingly, there was no need, much less any duty, for ViroPharma to disclose its contents. Additionally, claims based on the omission of information contained in the FDA's four earlier communications fail because these communications were part of an ongoing dialogue with the FDA that ViroPharma was not obligated to disclose to investors.

a. Nothing Was Hidden from Investors Because the Approval Letter Containing the Entire Label Was Publicly Available

There is no duty to disclose information that is otherwise publicly available. *Klein v. Gen. Nutrition Cos.*, 186 F.3d 338, 343 (3d Cir. 1999) ("Federal securities laws do not require a company to state the obvious," finding no claim based on alleged failure to disclose well-publicized worldwide vitamin E shortage); *Discovery Labs. I*, 2006 WL 3227767, at *10-11 (finding "compelling" the argument "that the information was already available in the marketplace," "prior public disclosure negates a finding that material information was withheld"); *In re Discovery Labs. Sec. Litig.*, No. 06-1820, 2007 WL 789432, at *3 (E.D. Pa. Mar. 15, 2007) ("*Discovery Labs. II*") ("the law does not require companies in regulated industries to append to every press release a tutorial on the applicable portion(s) of the Code of Federal Regulations"), *aff'd*, 276 F. App'x 154 (3d Cir. 2008).

Plaintiff alleges that the Approval Letter was the "culmination of what the FDA had been telling the Company all along," ¶ 16, and that it was not publicly available. ¶ 72, n.36 ("The December 14, 2011 Letter was . . . . [n]ot publicly available until after the Class Period [April 9, 2012]."). The allegation that the Approval Letter was not publicly available is demonstrably false. In fact, the December 14, 2011 Approval Letter was made public on the FDA website on December 15, 2011. Ex. 7, Forgues Aff. As a result, Plaintiff's entire omissions theory must fail given that "[t]he supposedly damning letter on which plaintiff's theory rests was publicly available on the FDA's website throughout the putative class period, where it could have been read and assessed by any investor." *Fort Worth Emp'rs' Ret. Fund v. Biovail Corp.*, 615 F. Supp. 2d 218, 221 (S.D.N.Y. 2009). Thus, ViroPharma was under no obligation to disclose the contents of the Approval Letter; it had already entered the public domain. *Silverstrand Invs.*, 2011 WL 3566990, at *7 (noting that "the defendants had no duty to disclose [certain information received from the FDA] because both action letters had already been publicly disclosed by the FDA prior to the Offering").

Not only was the Approval Letter public, but investors also unquestionably knew that a grant of exclusivity was subject to the FDA's review and decision. What neither ViroPharma nor the public knew at the time was exactly how the FDA would interpret the law. The QI Act had yet to be interpreted by the FDA or any court, and the company told investors that Vancocin was "likely a test case." Ex. 13, Feb. 28, 2012 Earnings Call Tr. at 7. Indeed, at least two analysts who followed ViroPharma reached a conclusion that differed from that reached by the company. Exs. 16, 17; *see also Plumbers and Pipefitters Local Union 719 Pension Fund v. Zimmer Holdings, Inc.*, 673 F. Supp. 2d 718, 743 (S.D. Ind. 2009), *aff'd,* 679 F.3d 952 (2012) (finding analysts' reports casting doubts on supposed adverse events for medical device supported defendants' argument that the failure to disclose such adverse events was not material). Thus, investors could draw their own conclusions from the public information about whether the new label would qualify for exclusivity.

b. There Was No Duty to Disclose the Four Communications with the FDA Prior to the Approval Letter

ViroPharma's prior communications with the FDA did not need to be disclosed because they reflected the company's ongoing dialogue with the FDA division charged with reviewing and approving label changes. *In re MedImmune, Inc. Sec. Litig.*, 873 F. Supp. 953, 966 (D. Md. 1995) ("Defendants, as a general proposition, had no duty to report its [sic] ongoing discussions with FDA during the review process"). As the *MedImmune* court noted under similar circumstances:

> Mere questioning by the FDA imposed no duty upon Defendants either to trim back their opinions . . . or to report to the public the FDA staffers' questions as they arose. ***Continuous dialogue between the FDA and the proponent of a new drug is the essence of the product license application process***. Questions may emanate from one or more [FDA] staffers in random or sporadic fashion. Many, if not all, questions presumably get answered in the process. ***Requiring ongoing disclosure of FDA's questions would not only be disruptive to the review process; it could easily result in misleading the public more than not reporting the questions.*** Where mere disclosure of a question might cause the company's stock to decline in value, the eventual answer to the question might cause it to rise once again.

Id. (emphasis added); *see also Gaer v. Educ. Mgmt. Corp.*, No. 10-1061, 2011 WL 7277447, at *22 (W.D. Pa. Aug. 30, 2011) ("Alleged risks arising out of potential changes to a regulatory framework fall squarely within the category of soft information and need not be disclosed."); *In re Sofamor Danek Grp., Inc.*, 123 F.3d 394, 402 (6th Cir. 1997) ("[P]redictions [about future regulatory actions] not 'substantially certain to hold,' like most matters of opinion, simply do not come within the duty of disclosure."). Accordingly, claims based on the alleged omission of information contained in these communications should be dismissed.

2. ViroPharma Did Not Fail to Disclose Material Information Related to the Communications with the FDA

Even assuming that ViroPharma did have some duty to disclose what was already public or was part of an ongoing regulatory process, which is denied, nothing in the Approval Letter or the four prior communications renders the company's statements false or misleading. Indeed, any materiality ascribed to any of the communications requires a hindsight application of the heightened standard that the FDA ultimately adopted—a standard that was not publicly known by ViroPharma or anyone else at the time.

a. The Approval Letter

The Approval Letter is silent about exclusivity under the QI Act or whether the changes to the label warranted such exclusivity. The challenged statements accurately summarized the changes to the label contained in the Approval Letter and then set forth the company's opinion why the new label met the statutory requirements for exclusivity; namely, that the newly approved label included updates "to the prescribing information for VANCOCIN with clinically relevant new safety and efficacy information." Ex. 2, Approval Letter at 1.

In addition, the Approval Letter itself contradicts some of Plaintiff's assertions such as Plaintiff's challenge that the label lacked "'meaningful safety and efficacy data.'" *See, e.g.*, ¶ 120. The Approval Letter explicitly noted that the label updates contain "clinically relevant new safety and efficacy information," Ex. 2, Approval Letter at 1, which data the FDA obviously considered "meaningful" enough to be "clinically relevant." Similarly, the new label (that was part of the Approval Letter) contained information about Vancocin's clinical success rate against the CDAD BI strain, *id.* at § 14 ("Clinical success rates were 87% for BI strain"), thus refuting Plaintiff's claim that the description of the label as including clinical safety and efficacy data for treating the BI strain was false. *See, e.g.*, ¶ 98.

In an effort to show that the Approval Letter contradicts ViroPharma's statements, Plaintiff points to statements in the Approval Letter regarding PREA to argue that the new label could not contain a "new indication" or "new dosing regimen" because such label claims would have required compliance with PREA. Plaintiff argues that the PREA statements in the Approval Letter were thus conclusive evidence that ViroPharma would not receive exclusivity under FDA's later-announced standard. In doing so, Plaintiff conflates the PREA criteria with the FDA's later announced definition of a new "condition of use." *See, e.g.*, ¶¶ 80, 90, 96.

Plaintiff's theory here is simply a red herring and more "fraud by hindsight." Whether a label change triggers a PREA compliance requirement does not address the critical question: are any of the label changes eligible for exclusivity under the QI Act? The answer, of course, turned on how the law ultimately would be interpreted by the FDA. Plaintiff's PREA argument is irrelevant unless the standard "to qualify Vancocin for an additional three years of exclusivity" was known by ViroPharma in December 2011 to be limited to "the approval of a new indication, new dosing regimen", ¶ 96(a), or some other PREA-triggering change that also would rise to the FDA's heightened standard of "a significant new use." Of course, that standard was announced for the first time four months later, in April 2012. It was not apparent from the Approval Letter (which was publicly available in any event) or anywhere else.

Moreover, by equating "condition of use" with the PREA criteria, Plaintiff is construing the QI Act even more narrowly than the FDA did. In the *Hamburg* litigation, the FDA argued and the court held that a "new indication" was just one example of the FDA's definition of a "significant new use." *Hamburg*, 2012 WL 1388183, at *15 ("The FDA cited a 'new indication' only as an ***example*** of a 'significant new use,' as evidenced by the fact that 'new indication' is contained in a parenthetical and introduced by the words 'such as.' The crux of the agency's interpretation is 'significant new use,' and by its terms it clearly includes more than just new indications.") (emphasis in original); *see also id.* at *15 n.24 (reiterating FDA's consistent view that "'conditions of use' . . . 'encompass how, to whom, and for which purposes a drug product is used'"). Plaintiff's mixing of statutory standards is nothing more than an inappropriate "apples to oranges" comparison.

The approved changes to Vancocin's label included a wholly new clinical studies section describing the studies and the data; a wholly new adverse reactions section; data and instructions regarding nephrotoxicity monitoring; efficacy against the BI strain; and instructions on use in the geriatric population. Ex. 9, CP Supplement at 6-7; *see* Ex. 2, Approval Letter at §§ 5.2, 5.3, 6.1, 8.5, 14 (December 14, 2011 sNDA approval enclosing the content of the approved label). While the FDA ultimately determined that those changes did not meet its heightened standard for exclusivity for old antibiotics, that standard simply was not known at the time.

Plaintiff cannot state a fraud claim by alleging that Defendants should have disclosed to investors that it did not meet a standard or definition that had not yet been announced. "Without allegations that Defendants' [understanding of exclusivity] contradicted either the FDA's definition or common industry usage, Defendants' statements regarding [exclusivity] could not have been false or misleading when made." *In re Adolor Corp. Sec. Litig.*, 616 F. Supp. 2d 551, 567 (E.D. Pa. 2009); *see also id.* at 566 ("Plaintiffs do not support their definitions with citations to FDA guidelines or assert that the definitions are the industry standard. These definitions are little more than conclusory allegations that we need not consider.").[11]

In sum, given that the Approval Letter did not address exclusivity, and that Plaintiff's falsity argument depends upon drawing after-the-fact inferences and relies upon the incorrect premise that only factors relevant to PREA could qualify as a new "condition of use," the Approval Letter does not render any challenged statement false when made.

b. The Four Earlier Communications with the FDA

Plaintiff's claims that information from the earlier FDA communications renders the challenged statements false fail because Plaintiff does not identify any contemporaneous statement by ViroPharma that was allegedly rendered misleading by information in these communications, and because issues in these communications were resolved as reflected in the Approval Letter. Moreover, there is nothing in the statute or the FDA's ultimate decision that

[11] Plaintiff's averments citing to the legislative history are insufficient to demonstrate that the standard for exclusivity had been established before the FDA's decision on April 9, 2012. Plaintiff suggests that one senator had stated that exclusivity would be available to old antibiotics "'provided they will be used for a new indication.'" ¶ 61. Plaintiff's reference to those comments, however, does not change the text of the QI Act, which does not define a new "condition of use." Moreover, the senator's comments were not in the context of defining what a new "condition of use" means under section 505(v) of the QI Act. And the FDA itself concedes that eligibility for exclusivity includes other "new use[s]" beyond indications. Ex. 18, Apr. 10, 2012 Press Release at 1.

suggests that issues raised in these prior communications (such as comparative claims) related to the criteria necessary to qualify for exclusivity.

First, none of the Defendants' statements that Plaintiff challenges was made contemporaneously with the four FDA communications. Indeed, the Complaint is devoid of any allegation that ViroPharma made any comments about exclusivity until the FDA approved the sNDA on December 14, 2011, at which time ViroPharma knew—and summarized in its press release—the changes to the label that the FDA had approved.

Second, once the Approval Letter was issued, information in the prior communications was not relevant because the Approval Letter made plain that the FDA reviewers had resolved their earlier concerns. *See*, *e.g.*, *Fort Worth,* 615 F. Supp. 2d at 221 (noting that plaintiffs' allegations about supposedly omitted information were refuted by their own pleading which noted the defendant submitted further applications to the FDA that never required the disputed information and made its findings publicly available on the FDA website). Thus, to the extent Plaintiff is suggesting that the earlier communications should have led ViroPharma to believe that the FDA would not permit ViroPharma to include efficacy data from the clinical trials, such inferences are rebutted by the fact that the sNDA was approved by the FDA and ***did*** include efficacy data. Ex. 2, Approval Letter. Plaintiff's reference to the lack of ***comparative*** efficacy data in the label is yet another irrelevant, diversionary tactic. The absence of "comparative" data in the label would only have relevance if (a) ViroPharma knew in advance that the FDA would interpret the limitation in the QI Act to require a "significance" threshold, and (b) comparative data would in fact be viewed as "significant."[12] In any case, the FDA's concerns about the use of

[12] Plaintiff's reference to the discussion of comparative claims impliedly suggests that the standard for such claims is identical to or is a necessary predicate to a finding of a new "condition of use." Plaintiff offers no support for this suggestion, and a review of the law demonstrates that no such equivalency can be argued. 21 C.F.R. §§ 355(j)(5)(F)(iv), 355(v). Moreover, the test ultimately adopted by the FDA for determining a new "condition of

comparative studies in the new label dropped out because ViroPharma did not seek to add comparative language to the new label. Ex. 5, May 24, 2011 Teleconference Minutes at 2 ("ViroPharma confirmed that no reference will be made to metronidazole in the Vancocin capsule labeling and that no comparative claims versus metronidazole are being proposed.").

Finally, there is nothing in these four communications that addressed the criteria necessary to qualify for exclusivity under the statute or that signaled the FDA's ultimate decision on the standard to apply. Thus, Plaintiff's allegations concerning the issues raised in ViroPharma's dialogue with the FDA reviewers do not establish that the failure to disclose these issues was a material omission or that the statements ViroPharma did make were materially misleading when made.

3. The Alleged Omissions from the Citizen Petition Supplement Are Immaterial

The arguments set forth above apply equally to doom Plaintiff's challenges to statements in the CP Supplement. ¶¶ 107-17; *see also* Compl. A-1 to A-4. As evident from the summary chart appended to the Complaint, Compl. A-1 to A-4, each of Plaintiff's claims as to the alleged omissions from or misstatements in the CP Supplement rest on the same flawed premise as Plaintiff's other claims, *i.e.,* that ViroPharma's arguments in its petition to the FDA were false and misleading because they omitted details from the four interim communications with the FDA (which were not material and ViroPharma had no duty to disclose) and/or were contradicted by the Approval Letter (which was already publicly available). Moreover, as discussed in Section III.B.2.g, above, the CP Supplement plainly was not a representation to the market that the FDA had granted exclusivity nor did it purport to assure investors that the grant was a "*fait accompli.*" By its very nature, the filing was confirmation that the FDA would make that decision, not

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use" says nothing about comparative efficacy. *See*, *e.g.*, ¶ 137.

ViroPharma. At that time, the FDA had not yet announced its heightened standard or applied it to Vancocin, and analysts' predictions about what the FDA would do differed. *See*, *e.g.*, Section III.C.1.a, *supra*.

* * *

For all of the foregoing reasons, the Complaint fails to allege any material misrepresentations or omissions and must be dismissed.

D. Plaintiff Fails to Allege Particularized Facts Giving Rise to a Strong Inference of Scienter

Finally, Plaintiff's claims must be dismissed for failure to allege particularized facts giving rise to a strong inference that Defendants acted intentionally or recklessly. *Avaya*, 564 F.3d at 267. Allegations of motive and opportunity are no longer an independent means to plead scienter in this Circuit. *Id.* at 276-77. "Recklessness" means "highly unreasonable" conduct: "'not merely simple, or even inexcusable negligence, but an extreme departure from the standards of ordinary care.'" *Advanta*, 180 F.3d at 531, 535 (cited in *Avaya*, 564 F.3d at 267 n.42). Scienter "requires a misrepresentation so recklessly made that the culpability attaching to such reckless conduct closely approaches that which attaches to conscious deception." *In re Digital Island Sec. Litig.*, 357 F.3d 322, 332 (3d Cir. 2004). Plaintiffs cannot simply allege an individual's position, *see*, *e.g.*, ¶¶ 152-53, and claim that he "'must have known' a statement was false or misleading[; these] are 'precisely the types of inferences which [courts], on numerous occasions, have determined to be inadequate.'" *Advanta*, 180 F.3d at 539.

1. Plaintiff Alleges No Particularized Facts that Defendants Knew or Were Reckless in Not Knowing that the FDA Would Deny Exclusivity

Plaintiff does not aver that anyone at the FDA explicitly told ViroPharma that the FDA would deny exclusivity. Instead, Plaintiff's allegations that Defendants knew or were reckless in not knowing that the new label did not qualify for exclusivity under the FDA's yet-to-be-announced heightened standard are based entirely on the five FDA communications with ViroPharma discussed above, *see*, *e.g.*, ¶¶ 96, 106, 111, 114-15, 119, 126, 129, 133, 157-59, and on the purported assertions of confidential witnesses. None of these allegations is sufficient to establish scienter for purposes of a Section 10(b) claim.

a. The FDA Communications Do Not Show a Strong Inference of Scienter

The five FDA communications do not support Plaintiff's position for two reasons.

First, on their face, they say nothing about exclusivity or a new "condition of use." Thus, Plaintiff badly misstates the import of the communications when it pleads that they "specifically inform[ed] Defendants that the new Vancocin label did not meet the criteria for exclusivity." *See, e.g.*, ¶ 121.

Second, the communications do not contain information that "Defendants clearly should have understood to mean that the new label did not meet the criteria for three years of exclusivity." ¶ 129; s*ee also* ¶¶ 126, 133. As discussed in Section III.C.2, *supra*, the Complaint provides no factual basis showing that these communications told or should have told Defendants anything about how the FDA would later interpret the QI Act or whether the changes to the Vancocin label would meet that standard. Indeed, the *Hamburg* litigation confirms that the FDA's interpretation of the QI Act was a case of first impression, that the statute was ambiguous (at best) and that the FDA ultimately applied a new and higher standard. *Hamburg*, 2012 WL 1388183, at *8 ("[t]he QI Act does not expressly define what constitutes a condition of use . . . approved before the date of enactment," and describing the FDA's conclusion that "there is a higher hurdle for exclusivity for an Old Antibiotic than there is for another kind of product seeking 3–year exclusivity"); *see also id.* at *12 (determining that "it [is] likely that the statute is ambiguous" because the QI Act "does not address what constitutes a 'condition of use'" and "[s]tarting with the plain meaning of the text and looking to the language itself, 'condition of use' is not defined").

At bottom, Plaintiff is trying to infer knowledge or recklessness with respect to the FDA's ultimate denial of exclusivity premised on the notion that ViroPharma somehow knew FDA's standards for exclusivity under the QI Act before FDA ever described them. This is classic, impermissible fraud by hindsight. *Winer*, 503 F.3d at 331-32 (rejecting fraud by hindsight); *Discovery Labs. II*, 2007 WL 789432, at *5-6 (same); *see also Casula v. athenahealth, Inc.*, No. 10-10477, 2011 WL 4566115, at *6-7 (D. Mass. Sept. 30, 2011) (finding plaintiff failed to raise a strong inference of scienter where, although plaintiff contended that the SEC's guidance on the accounting rule defendants allegedly violated was "'simple and straightforward,'" this guidance was "nuanced" and "subject to evaluation [] on a 'case-by-case'" basis); *Noble Asset Mgmt.*, 2005 WL 4161977, at *13 (scienter not supported by allegations that defendants supposedly knew the FDA would not approve the company's submission where the "FDA's response to the [company] was not a foregone conclusion").

b. The Allegations Based on Confidential Witnesses Do Not Show Scienter

The Complaint's allegations regarding the views of confidential witnesses ("CWs") are also insufficient to establish that ViroPharma knew or was reckless in not knowing how FDA would act. Further, none of the CWs meet this Circuit's standards for anonymous witness allegations as established in *California Public Employees' Retirement System v. Chubb Corp.*, 394 F.3d 126 (3d Cir. 2004).

First, the CWs' allegations are not tethered to the challenged statements. CW6 is not alleged to be an employee of ViroPharma, ¶ 68 n.34, and Plaintiff has not drawn any connection between him and any Defendants. *Chubb*, 394 F.3d at 149 (discounting testimony from a CW who was not an employee of the company). Similarly, the statements attributed to former employees CW1, CW2 and CW3 consist of vague comments about ViroPharma's business; no allegations about exclusivity are attributed to those CWs and Plaintiff does not contend that they had contact with the individual defendants. ¶¶ 41, 70, 89, 152, 153. *Chubb*, 394 F.3d at 149 (rejecting plaintiff's efforts to "cite to low-level, locally sited former employees without alleging how or why such employees would have knowledge that expanded beyond what the vague descriptions suggest to substantiate the claim that [material information was not disclosed]").

Second, the CWs' allegations are not reliable. Statements by CW2, CW4 and CW5 about ViroPharma's belief in December 2011 that the new Vancocin label qualified for exclusivity should not be credited because these individuals left ViroPharma no later than August 2011, well before the alleged events that are the subject of the Complaint. ¶¶ 41 nn.9 & 11, 70 n.35; *see also Chubb*, 394 F.3d at 148. Assertions attributed to CWs 1-4 also fail to meet the applicable standard because Plaintiff does not allege anything to suggest how the positions held by these witnesses demonstrate that they knew the information alleged. *Id.* ("[t]he lack of allegations regarding how or why such employees would have access to the information they purport to possess is problematic"); *see also id.* at 149 (dismissing CW testimony from individuals at different parts of the company without allegations demonstrating how these witnesses possessed the information about the alleged fraud). CWs 1-4 are identified in the Complaint as being responsible for "sales" teams or "marketing," ¶ 41 nn.8-11, but the Complaint fails to demonstrate why individuals serving in such roles would have any knowledge about the regulatory exclusivity of Vancocin. As such, none of these allegations are sufficient. *Chubb*, 394 F.3d at 150-51; *cf. Avaya*, 564 F.3d at 263 (concluding that plaintiffs' confidential witness allegations were sufficient when plaintiffs "'appropriately described the positions formerly held by each of [the confidential] sources as well as the basis of the sources' personal knowledge.'"). These deficiencies mean that the CWs may not be used to support Plaintiff's efforts to plead scienter. *Avaya*, 564 F.3d at 263 ("If anonymous source allegations are found wanting with respect to these criteria, then we must discount them steeply.").

At most, even crediting the CWs' unreliable statements, all that the Complaint alleges is that the individual defendants were involved in the approval process and would have been aware of the FDA communications. However, as discussed above, this vague averment is not sufficient to establish that the individual defendants knew or were reckless in not knowing that the FDA would eventually interpret the phrase "condition of use" in the way that it did.

Accordingly, whether Plaintiff tries to infer scienter from the FDA communications or the CW allegations, the Complaint lacks the requisite particularized facts supporting a strong inference of scienter.

2. Plaintiff's Theory of Scienter Is Irrational

Plaintiff's theory of scienter also fails because it makes no sense. Ultimately, no matter what ViroPharma said about obtaining exclusivity, it was the FDA that had the final say on this issue—a point that ViroPharma emphasized in its communications with the investing public. *E.g.*, Ex. 8, Dec. 14, 2011 Press Release at 4. Thus, if ViroPharma knew that it would not get approval, as Plaintiff alleges, it also had to know that the "truth" would be disclosed when the FDA announced its decision. As the Third Circuit has recognized, "'[p]eople sometimes act irrationally, but indulging ready inferences of irrationality would too easily allow the inference that ordinary business reverses are fraud.'" *In re Burlington Coat Factory*, 114 F.3d at 1418 (quoting *DiLeo v. Ernst & Young*, 901 F.2d 624, 629 (7th Cir. 1990)). The allegations in the Complaint about the importance of Vancocin to ViroPharma, ¶¶ 38-43, do not support the irrational argument that the company made statements about future exclusivity that the company knew to be false and knew would be disclosed as false in a matter of months. *In re CDnow, Inc. Sec. Litig.*, 138 F. Supp. 2d 624, 642-43 (E.D. Pa. 2001) (rejecting as implausible plaintiff's scienter theory that defendants concealed the company's true financial condition in order to artificially inflate stock prices over a class period of less than two months; holding that "a plaintiff must show concrete benefits that could be realized as a result of a defendant's deceptive practices"); *In re Citrix Sys. Sec. Litig.*, No. 00-6796, 2001 U.S. Dist. LEXIS 25351, at *12 (S.D. Fla. Sept. 29, 2001) ("[A]llegations of misleading statements or omissions that lead to temporary inflation of stock price that run contrary to a defendant's 'informed economic self-interest,' have been held insufficient for scienter, even prior to the PSLRA.").

Plaintiff's irrational theory is further undermined by the extensive risk disclosures ViroPharma issued. As numerous courts have recognized, "attempts to provide investors with warnings of risks generally weaken the inference of scienter." *Ezra Charitable Trust v. Tyco Int'l, Ltd.*, 466 F.3d 1, 8 (1st Cir. 2006); *accord In re Worlds of Wonder Sec. Litig.*, 35 F.3d 1407, 1425 (9th Cir. 1994); *Weiss v. Priceline.com, Inc.*, 330 F. App'x 230, 232 (2d Cir. May 22, 2009). It makes no sense that Defendants would draw attention to and warn the market of the risk of the very problem they supposedly knew would occur.

3. Stock Sales Alone Do Not Suffice to Plead Scienter

Lacking any other basis to support its irrational scienter theory, Plaintiff suggests that a strong inference of scienter may be inferred based on two of the individual defendants' sale of ViroPharma stock during the putative class period. However, the Third Circuit has made clear that absent other well pleaded facts of scienter, allegations of motive, including stock sales, are insufficient to establish scienter. *Avaya*, 564 F.3d at 276-77. Thus, Plaintiff's reference to the stock sales by Defendants Doyle and Rowland are simply not sufficient to show scienter.

Moreover, Plaintiff's motive allegations are undermined by the fact that the two other individual defendants—including Milano, the company's CEO, who made many of the challenged statements—did not sell stock, thus negating any claim that the individual defendants intentionally misled the market for personal profit. *See, e.g.*, *In re Cybershop.com Sec. Litig.*, 189 F. Supp. 2d 214, 234 (D.N.J. 2002) (noting that the fact that one of the named defendants did not sell stock weighed against an inference of fraud). If Plaintiff's alternate theory were true, *i.e.*, that the individual defendants engaged in a "scheme" to defraud investors, then logically each individual defendant should have divested all of his holdings. Plaintiff cannot, and does not, allege that happened. None of the individual defendants sold all of his ViroPharma shares and, as noted, two of the four individual defendants did not sell any stock during the class period.

In addition, as discussed, ViroPharma engaged in a substantial stock repurchase program before and during the class period. Exs. 14, 15. Not only did ViroPharma continue its share repurchase program during the class period, but in March 2012 it increased the number of shares it purchased by 60% as compared to the previous quarter—buying 1.6 million shares for $50 million—despite the fact that the share price had risen substantially and the stock was trading near its class period high. Ex. 15, May 1, 2012 10-Q at 47 (stock repurchases in March 2012 at an average price of $31.13); ¶ 160 (alleging "Class Period high of $33.17"). That is clearly not the action of a company that knew its stock price was inflated, and such action belies an inference (much less a "strong inference") of scienter. *See*, *e.g.*, *Adolor*, 616 F. Supp. 2d at 572-73 (noting that defendants increased their holdings throughout the class period and that "[s]uch conduct raises a compelling inference ***against*** scienter" (emphasis in original)); *Zimmer*, 673 F. Supp. 2d at 748 ("'[S]tock repurchase programs actually ***negate*** a finding of scienter.'")

(quoting *In re Tibco Software, Inc.*, No. C 05-2146, 2006 WL 1469654, at *21 (N.D. Cal. May 25, 2006)) (emphasis in original).

4. Any Weak Inference of Scienter Is More Than Offset by the Competing Inferences

The more rational and compelling inference from the facts pled in the Complaint is that Defendants genuinely believed in the likelihood that Vancocin would be granted exclusivity, but recognized and disclosed that the FDA controlled the decision and might conclude otherwise. The fact that the FDA later denied exclusivity based upon a novel interpretation of a statutory provision that the *Hamburg* court found to be ambiguous certainly is not sufficient to meet Plaintiff's burden of pleading facts demonstrating a strong inference of scienter. *Zucker v. Quasha*, 891 F. Supp. 1010, 1017 (D.N.J. 1995) (holding that an omission that is "misleading only in hindsight" cannot form the basis of a securities claim).

* * *

Accordingly, no strong inference of scienter has been pled and the Complaint should be dismissed on this ground as well.

E. Because Counts I and II of the Complaint Fail to State a 10b-5(b) Claim, the Complaint Also Fails to State 10b-5(a) and 10b-5(c) Claims and Count III (Section 20(a) Claim) Also Fails

Plaintiff alleges that Defendants are also liable for scheme liability under Section 10b-5(a) and 10b-5(c), but because Plaintiff has failed to plead facts to support a claim under Section 10b-5(b), such claims must also fail. *S.E.C. v. Lucent Techs., Inc.*, 610 F. Supp. 2d 342, 358-61 (D.N.J. 2009) (dismissing Section 10b-5(a) and (c) claims where the "allegations of a scheme [were] based on the same misstatements that would form the basis of a misrepresentation claim under Rule 10b-5(b)"); *Anadigics,* 2011 WL 4594845, at *34 (same). Likewise, the Section 20(a) claim for control person liability must be dismissed because, as explained above, Plaintiff has failed to state an actionable Section 10(b) claim. A plaintiff's failure to allege a primary violation of Section 10(b) is fatal to control person claims under Section 20(a). *Chubb*, 394 F.3d at 159 n.21 ("The lack of any predicate violation of the Securities Exchange Act of 1934 compels dismissal of control person claims.").

IV. CONCLUSION

For the foregoing reasons, Defendants respectfully request that the Court grant their motion to dismiss the Complaint.

December 20, 2012

Respectfully submitted,

/s/ Steven A. Reed

Marc J. Sonnenfeld (I.D. No. 17210)
J. Gordon Cooney, Jr. (I.D. No. 42636)
Steven A. Reed (I.D. No. 60145)
MORGAN, LEWIS & BOCKIUS LLP
1701 Market Street
Philadelphia, PA 19103-2921
Telephone: 215.963.5000
Facsimile: 215.963.5001

Attorneys for Defendants

CERTIFICATE OF SERVICE

The undersigned hereby certifies that on December 20, 2012, true copies of the foregoing Motion to Dismiss and supporting Memorandum of Law were served on the following counsel via the Court's ECF system and electronic mail.

Jonathan Gardner
jgardner@labaton.com
Carol C. Villegas
cvillegas@labaton.com
Iona M. Evans
ievans@labaton.com
LABATON SUCHAROW LLP
140 Broadway
New York, NY 10005
Telephone: (212) 907-0700
Facsimile: (212) 818-0477

David W. Mitchell
davidm@rgrdlaw.com
ROBBINS GELLER RUDMAN & DOWD LLP
655 West Broadway
Suite 1900
San Diego, CA 92101
Telephone: (619) 231-1058
Facsimile: (619) 231-7423

Paul J. Scarlato
scarlato@gskplaw.com
Brian D. Penny
penny@gskplaw.com
GOLDMAN SCARLATO KARON & PENNY, P.C.
101 E. Lancaster Ave.
Suite 204
Wayne, PA 19087
Telephone: (484) 342-0700
Facsimile: (484) 580-8729

/s/ Laura E. Hughes
Laura E. Hughes